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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BURK, CATHERINE E

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/018,619	Applicant(s) FRITZ ET AL.	
	Examiner CATHERINE E. BURK	Art Unit 4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>19 May 2003, 9 March 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 55-60 are objected to because of the following informalities: There are two claims with the number 55, the first one should be numbered 54. Claims 55-60 are objected to as being dependent on claim 54, while currently there is no claim 54. For this office action, the first claim 55, "A method for vascular radiation treatment comprising..." will be referred to as claim 54. Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 31-37, 41 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Coniglione (US 5713828 A).

3. Regarding claims **31** and **32**; Coniglione discloses hollow tube brachytherapy devices (100) (radiation sources) comprising a seed substrate (101) comprising a radiation emitting layer (104) that is enclosed with a sealing layer (106), to form a capsule, as a means of containment of said radiation emitting layer (col.4, lines 18-25). The seeds are sequentially, directly, and movably linked to each other via suture

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material, rigid rods, or other biocompatible connecting members (col. 4, lines 55-59 and fig. 4).

4. Regarding claim **33**; the components of the device may be made of titanium (col. 4, lines 32-33).

5. Regarding claims **34** and **35**; seed substrate (101) is contained within radiation source (100). Both have an elongate shape and share the same (and therefore parallel) axis of elongation (fig. 1).

6. Regarding claims **36** and **37**; suitable radioisotopes for use in the radiation emitting layer include Pd^{103} , a gamma-emitting substance.

7. Regarding claims **41** and **48**; suture materials, rigid rods, or other biocompatible connecting members mechanically link the seeds together by forming a flexible single joining member that extends through the length of the radiation source (fig. 4).

8. Claims 49 and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinberger (US 5503613 A).

9. Regarding claim **49**; Weinberger discloses a catheter apparatus (5) with proximal and distal end portions and a lumen (7) extending there-between for receiving radiation source(s) (8d-f) coupled to a transfer wire (8). The radiation sources (8d-f) may be in the form of a pellet, or seed as a means for containing radiation emitting material (col. 4, lines 10-12). Fig. 4 shows radiation sources (8d-f) sequentially, directly, and movably linked to the transfer wire (8). Catheter (5) also comprises a guide wire (9) in a separate lumen (6).

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10. Regarding claims **54-56**; Weinberger discloses a method of radiation treatment comprising directing an elongated catheter (5) with proximal and distal end portions and a lumen (7) extending there-between for receiving radiation source(s) (8d-f) to a treatment site by way of a guide wire (9) in a separate lumen (6). (col. 7, lines 7-13). The radiation sources (8d-f) may be in the form of a pellet, or seed, as a means for containing radiation emitting material (col. 4, lines 10-12). Fig. 4 shows radiation sources (8d-f) sequentially, directly, and movably linked to a transfer wire (8). The transfer wire (8) is inserted (by pushing as in claims 55 and 56) into the proximal end of the lumen (7) toward the distal end until the target treatment area is reached. The sources (8d-f) are left in place until a desired dosage of radiation has been delivered and then the transfer wire (8) is retracted (by pulling as in claims 55 and 56) from the balloon catheter (col. 7. lines 21-30).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 38-40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coniglione (US 5713828 A) in view of Smith (US 3515876 A).

13. Regarding claims **38, 39** and **42**; Coniglione discloses wherein the seeds are mechanically linked, as described in regard to claim 41 above. Coniglione fails to

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disclose wherein the seeds are linked by magnetic *and* mechanical forces to each other and/or to a transfer wire and wherein means for containment comprises a magnetizable material.

However, Smith discloses radioactive source pellets (30 or 40) with magnetic jackets (41), made from magnetizable material, that allow the pellets to link to each other by magnetic forces to form trains (col. 4, lines 52-65 and figs. 3 and 4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to link the seeds of Coniglione together using magnetic forces, as taught by Smith.

Doing so would provide a seed strand that maintains seeds at evenly spaced distances along the joining member to better regulate treatment doses.

14. Regarding claim **40**; Coniglione fails to disclose wherein the seeds have rounded or spherical end caps on one or both ends.

However, Smith discloses spherical bumpers (43) at each end of the pellets (40) (col. 4, lines 62-66)

It would have been obvious to one of ordinary skill in the art at the time of the invention to include the spherical bumpers of Smith on the seeds of Coniglione.

Doing so would reduce friction between adjacent seeds and provide seeds that can slide more freely around curves in a catheter or conduit tube (Smith, col. 4, lines 63-65).

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15. Claims 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coniglione (US 5713828 A) in view of Slater (US 6273851 B1).

16. Regarding claims **43**, **44**, and **46**; Coniglione fails to disclose wherein the seeds comprise male and female means for coupling wherein the female means for coupling receives the male means for coupling of the following or preceding seed.

However, Slater discloses radioactive therapeutic seeds that comprise male and female means for coupling. Figure 3 shows seeds (10a) with male means for coupling provided on one end (46a), in the form of a hook, and female means for coupling provided on an opposite end (48a), in the form of a loop, and joined by a link (50a). However, Slater also discloses that two seeds may be coupled together by coupling male and female mating structures of different seeds to each other, without the need for a link (50a) (col. 6, lines 22-39).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Coniglione's invention to include the male/female connecting means of Slater.

Doing so would provide a seed strand that has a more controllable and isotropic radiation pattern (Slater, col. 3, lines 31-33) than loose seeds.

17. Regarding claims **45** and **47**; Coniglione fails to disclose wherein the connecting means comprises a head and receiving section, nor does Coniglione disclose wherein the connecting means comprise a hook and a second hook or loop.

However, Slater also discloses wherein the connecting means is a ball joint, in accordance with claims 45 and 47, comprising a head (46c and 48c) (male means) and

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a receiving section (62c and 64c) (female means) in the form of a hollow space (fig. 5). Slater also discloses that two seeds may be coupled together by coupling male and female mating structures of different seeds to each other, without the need for a link (50c) (col. 6, lines 22-39); therefore, the receiving section (62c and 64c) can be formed directly on the end of the seed from extensions of the means for containment of the radioactive material.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Coniglione's invention to include the ball joints of Slater.

Doing so would provide a seed strand that has a more controllable and isotropic radiation pattern (Slater, col. 3, lines 31-33) than loose seeds.

18. Claims 50-53 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberger (US 5503613 A) in view of Coniglione (US 5713828 A).

19. Regarding claims **50-52**, and **60**; Weinberger fails to disclose the physical properties of the seeds that are implanted using their device.

However, Coniglione discloses hollow tube radiation sources (100) comprising a seed substrate (101) comprising a radiation emitting layer (104)) that is enclosed with a sealing layer (106), to form a capsule, as a means of containment of said radiation emitting layer (col.4, lines 18-25). Both the seed substrate (101) and radiation source (100) have an elongate shape and share the same (and therefore parallel) axis of

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elongation (fig. 1). Coniglione also discloses wherein the radiation source (100) has a radiographically detectable band (col. 8, lines 60-63), in accordance with claim 52.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Weinberger to include the radiation sources of Coniglione.

Doing so would be substituting one type of brachytherapy seeds for an obvious equivalent.

20. Claims 53 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberger (US 5503613 A) in view of Smith (US 3515876 A).

21. Regarding claims **53** and **57**; Weinberger fails to disclose wherein the seeds are linked to each other by magnetic forces and the transfer wire comprises a magnet to push and pull the radiation sources.

However, Smith discloses radioactive source pellets (30 or 40) with magnetic jackets (41) that allow the pellets to link to each other by magnetic forces (col. 4, lines 52-65 and figs. 3 and 4). Smith also discloses a method of inserting and retracting the magnetic pellets from the device. The pellets are held in place, or supported using a toroidal magnet (35) to attract the magnetic pellet train. In order to remove the pellets from the device, the toroidal magnet (35) is broken away from the grip of the pellet and the pellet train is allowed to retract (col. 4, lines 32-51).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of inserting and removing Weinberger's seeds and transfer wire to include the magnetic properties of Smith.

Doing so would provide a method that can be automated with minimal mechanical and/or moving parts (Smith col. 2, lines 15-17).

22. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberger (US 5503613 A) in view of Good (US 6099457 A).

23. Regarding claim **58**; Weinberger fails to disclose wherein the radiation source is moved by applying an external magnetic field.

However, Good discloses radioactive seeds containing a ferromagnetic material that may cause movement of the seeds by externally applied magnetic fields (col. 8, lines 4-6).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Weinberger in view of Good.

Doing so would provide a method that enables force to be applied to the seeds to move it around using externally radiated energy to avoid damage to tissue (col. 7, lines 65-67).

24. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberger (US 5503613 A) in view of Slater (US 6273851 B1).

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25. Regarding claim **59**; Weinberger discloses a transfer wire (8) linked to radiation sources (8d-f). Weinberger fails to disclose wherein the transfer wire comprises a male of female means for coupling linked to the radiation source by engagement with the complementary means for coupling on the terminal end of the seeds thereof.

However, Slater discloses radioactive therapeutic seeds that comprise male and female means for coupling. Figure 3 shows seeds (10a) with male means for coupling provided on one end (46a) and female means for coupling provided on an opposite end (48a).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Weinberger's transfer wire to include means for coupling with the radiation sources of Slater.

Doing so would allow a user to move more than one type of radiation source or seed through the lumen of an implant catheter.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the applicant's claimed and disclosed invention. Radioactive seed chains without magnetic links: Visscher (US 7008367 B2), Drobniak (US 6969344 B2), Lowery (US 6949064 B2). Links driven by magnetic forces: van't Hooft (US 4233517 A) and Jensen (US 3706158 A). Male/female connectors: Sioshansi (US 6030333 A). Implant catheters: Hoff (US 3993058 A) and Silverman (US 3589356 A).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE E. BURK whose telephone number is (571) 270-7130. The examiner can normally be reached on Monday-Thursday 8:30 AM - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571) 272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CATHERINE E BURK/
Examiner, Art Unit 4185

/Terrell L Mckinnon/

Supervisory Patent Examiner, Art Unit 4185